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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|-------------------------------|
| 10/647,977 | 08/25/2003 | Barry D. Kuban | 895,675-004 | 2832 |
| 72286 | 7590 | 06/10/2010 | | |
| LEYDIG, VOIT & MAYER, LTD TWO PRUDENTIAL PLAZA, SUITE 4900 180 N. STETSON CHICAGO, IL 60601-6731 | | | | EXAMINER CHENG, JACQUELINE |
| | | ART UNIT 3768 | | PAPER NUMBER |
| NOTIFICATION DATE | | DELIVERY MODE | | |
| 06/10/2010 | | ELECTRONIC | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Chgpatent@leydig.com

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/647,977 | KUBAN ET AL. |
| | Examiner | Art Unit |
| | JACQUELINE CHENG | 3768 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 April 2010.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3-14,16-19,21-26,28-37 and 39-47 is/are pending in the application.
 - 4a) Of the above claim(s) 47 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,3-14,16-19,21-26,28-37 and 39-46 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 6, 2010 has been entered.

Response to Arguments

2. Applicant's arguments filed April 6, 2010 with respect to the added claim limitations of moving the data-gathering probe through a blood vessel at a substantially constant speed for independent claims 11, 19, 31 and 39 and their dependent claims have been fully considered but they are not persuasive. The examiner believes that the embodiment of the automated pull-back of the IVUS catheter in Slager (US 5,771,895) wherein the catheter is pulled back in 1 mm steps in response to an ECG or respiration trigger (col. 6 line 20-22), for example being pulled back at each detection of an R wave, is still being pulled back at a substantially constant speed. A person's ECG cycle and respiration cycle is substantially constant. For example between each R wave of a patient can be about 1 second, so in such a patient the catheter is being pulled back 1 mm every R wave, which occurs at a substantially constant rate of every second, so at a substantially constant speed of 1 mm/second. It is for these reasons believed that the previous

rejection for claims 11-14, 16-19, 21-26, 28-37, 39-41, and 43-46 dated August 6, 2009 still stands.

3. Applicant's arguments filed April 6, 2010 with respect to the rejection of independent claim 1 and its dependents under 35 U.S.C. 103(a) in regards to the added claim limitations of wherein the analysis of the blood vessel is utilized to classify vascular plaque of the blood vessel have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made further in view of Tu (US 2001/0007940 A1).

4. Also the examiner has noticed that the applicant does have support for the previous added limitation of without post processing selection of desired blood-vessel data and so a new new matter grounds of rejection is made.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. **Claims 1, 11, 19, 31, and 39** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The examiner could not find support for the amendments dated June 22, 2009. Although the cited paragraph, paragraph 0009 of the Applicant's published application,

does have support for permitting analysis of the blood vessel as if the blood vessel was standing still, it does not provide support for permitting analysis of the blood vessel without post processing selection of the desired blood-vessel data. Support for this limitation was also not found in other paragraphs of the applicant's specification.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. **Claims 11-14, 16-19, 21-26, 28, 29, 31-35, 37, 39, 40, and 43-46** are rejected under 35 U.S.C. 103(a) as being unpatentable over Praise (US 6,148,095) in view of Slager (US 5,771,895).

9. Praise discloses a system and method of acquiring blood vessel data in the form of images comprising an intravascular ultrasonic (IVUS) catheter, data-gathering and processing devices of a data fusion unit on a programmed computer, and a data storage unit (col. 4 line 8-35). The IVUS catheter is withdrawn at a fixed (substantially constant) speed with a pullback device such as a catheter driver while images (data) of the blood vessel are gathered (col. 5 line 5-8). To suppress heart and breathing motions in the images a gated image acquisition can be used (col. 11 line 41-55) such as by correlating the images taken with acquired ECG data. Only images that are taken during a certain heart phase (cyclical portion of heartbeat data common to multiple sets of heartbeat data) are used to reconstruct a 3D image to ensure the images being

utilized are taken under consistent conditions (as if the blood vessel was standing still) (col. 6 line 24-33). Although Pause does not explicitly disclose using ECG *triggered* image acquisition this acquisition method is well known in the art and it is often taught that either method can be used such as disclosed by Slager. Slager discloses a system and method of obtaining an accurate 3D reconstruction of a blood vessel using an IVUS with rotational transducers wherein either ECG gated or ECG triggered data can be used (abstract, col. 5 line 7-28). It would be obvious to use the triggering method instead of the gating method for the purpose of the sequence of cross-sectional ultrasound images can be immediately stacked without having to sort through a number of images, discarding the distorted images (permitting analysis of the blood vessel without post processing selection of desired blood-vessel data).

10. Pause also does not disclose that the transducer is adapted to rotate, but it would be obvious to one skilled in the art to use any comparable IVUS system with the system of Pause. Slager discloses such an IVUS system in which the transducers can rotate (col. 6 line 50-55) and wherein the rotational orientation can be identified (col. 3 line 50-54). So therefore it would be obvious to one skilled in the art at the time of the invention to combine Slager with Pause to further the utility of Pause to obtain data from any particular desired angle of the blood vessel and to quicken the image stacking time without having to sort through unneeded images.

11. **Claims 1, 3, 5-9, and 42** are rejected under 35 U.S.C. 103(a) as being unpatentable over Pause (US 6,148,095) in view of Slager (US 5,771,895) in view of Tu (US 2001/0007940 A1).

12. Pause and Slager discloses most of what is claimed as discussed above except for explicitly disclosing what the resulting image that is created is being used for. Pause does

generally talk about the desirability of using IVUS is for qualitative and quantitative assessment of the coronary arterial wall such as determining an amount and composition (classification) of plaque. Tu further discloses using images taken from a pull-back IVUS method to identify (classify) plaque at risk of rupture (vulnerable plaque) (paragraph 0047-0049). It would therefore be obvious to use the images of Prause to identify plaque at risk of rupture such as disclosed by Tu for the purpose of locating areas that need treatment.

13. **Claim 41** is rejected under 35 U.S.C. 103(a) as being unpatentable over Prause in view of Slager, as applied to claim 39 above, and further in view of Vince (US 6,200,268 B1).

14. **Claim 4** is rejected under 35 U.S.C. 103(a) as being unpatentable over Prause in view of Slager in view of Tu, as applied to claim 1 above, and further in view of Vince.

15. Neither Prause nor Slager for claim 41, or Prause nor Slager nor Tu for claim 4 discloses a plurality of transducers spaced circumferentially, but it would be obvious to one skilled in the art to use any comparable IVUS system with the system of Prause. Vince discloses such an IVUS system that comprises an array of transducers circumferentially positioned (col. 3 line 50-53) so therefore it would be obvious to one skilled in the art at the time of the invention to combine Vince with Prause to further the utility of Prause to obtain data from any angle of the blood vessel without having to spend time rotating the catheter to position the transducer in the correct direction.

16. **Claims 30 and 36** are rejected under 35 U.S.C. 103(a) as being unpatentable over Prause in view Slager in view of Tu, as applied to claims 19 and 31 above, further in view of Dias (US 5,284,148).

17. **Claim 10** is rejected under 35 U.S.C. 103(a) as being unpatentable over Prause in view Slager in view of Tu, as applied to claim 1 above, further in view of Dias.

18. Neither Prause nor Slager for claims 30 and 36, or Prause nor Slager nor Tu for claim 10 discloses acquiring the blood vessel data when the transducer is rotationally orientated in a predetermined location. In the same field of endeavor of IVUS imaging, Dias discloses an intravascular probe wherein the probe is rotated to a predetermined position and takes measurements (images) while at that predetermined position (col. 3 line 1-6). It would be obvious to start imaging at a particular rotational orientation such as disclosed in Dias in the invention of Prause for the purpose of if there is a particular region of interest that is wanted to be imaged the transducer would need to be rotationally orientated in the correct (predetermined) direction/location.

Conclusion

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE CHENG whose telephone number is (571)272-5596. The examiner can normally be reached on M-F 10:00-6:30.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacqueline Cheng/
Examiner, Art Unit 3768